

# **COVID-19 Therapeutics Provider Weekly News Digest**

**June 5<sup>th</sup>, 2023**

72<sup>nd</sup> Edition

## **NEW: Enhanced HPOP Launch Date Set for June 20 and Effect on Ordering and Allocations**

HPOP is scheduled to go live Tuesday, June 20, at 8 a.m. ET. There will be a **brief pause from 9:00 p.m. ET June 14 to 8 a.m. ET June 20** to allow HPOP to migrate the data to the new system and ensure everything is working properly before launch. During this time, ordering will still be available.

- After June 20, the enhanced HPOP will optimize medical countermeasure ordering and distribution and enable faster response times during future public health emergencies.
- All steps have been taken to ensure a smooth transition for current HPOP users, requiring minimal effort to onboard onto the new system. All data and settings in the current HPOP will be migrated to the enhanced HPOP.

Provider sites have been informed of the launch date and reauthentication details in a separate email.

### **Ordering Guidance Between June 14-20**

We understand a need for COVID-19 therapeutics may arise in some communities during the pause. ASPR will continue to do everything possible to ensure access to therapeutics continues during the HPOP pause.

### **COVID Therapeutics**

While HPOP ordering is paused, HPOP support will take email and phone orders for those communities who have an immediate critical need. To order COVID-19 therapeutics email [HPOP.Support@hhs.gov](mailto:HPOP.Support@hhs.gov) or call 833-868-6386. To order COVID-19 vaccines or diagnostics-email [cars\\_helpdesk@cdc.gov](mailto:cars_helpdesk@cdc.gov) or call 833-748-1979.

### **Reauthentication in HPOP**

On June 5, **current HPOP users will receive a reauthentication notification from [no-reply@mailers.us-langley-1.identity.idcs.oci.oraclegovcloud.com](mailto:no-reply@mailers.us-langley-1.identity.idcs.oci.oraclegovcloud.com)**. Please add this email address to your approved senders list so the reauthentication email and future account security notifications will not be blocked by your spam filters. After successfully registering, users will be taken to a page with a message congratulating them for successfully

## **Provider Resources**

Access provider resources by visiting the [Information for COVID-19 Therapeutics Providers](#) page.

Review answers to commonly asked provider questions in the [FAQ for Therapeutics Providers](#).

Access the [COVID-19 Outpatient Therapeutics Videos | HHS/ASPR](#) which describes treatment options for your patients as well as ASPR's work to help ensure that these products are distributed equitably across the United States.

## **Federal Resources**

### **New cadence:**

HHS/ASPR COVID 19 Therapeutics Stakeholder Meeting State/Territorial Health Officials Nat'l Health Care Med Orgs/Associations Every 2 weeks on Wednesdays from 1:00 - 2:00PM CT. Next session- May 31

### **New cadence:**

HHS/ASPR Office Hours every 2 weeks on Wednesdays from 2:30 - 3:00 PM CT. Next session- June 7

### **New cadence:**

Health Partner Ordering Portal (HPOP) Office Hour COVID 19 Therapeutics and Mpox combined- every three weeks/Thursday (3:00-4:00PM CT) Paused until after launch

### **New cadence:**

reauthenticating, but they will not be able to access any application data until Tuesday, June 20. Contact HPOP support if any current users do not receive the email and one will be sent to you.

### **Training and Office Hours**

We will continue with training sessions during the two weeks prior to launch of the enhanced HPOP system, June 6 – June 16. There will be three training sessions for provider site HPOP users each week. Each training session can accommodate 1,000 attendees, and registration will close for sessions when it has reached capacity.

In addition to the live virtual training sessions, a recorded training session and short on-demand video tutorials will be available in HPOP by clicking “Help.”

Thank you for your continued partnership as HHS enhances ordering and distribution of medical countermeasures and other resources during public health responses.

For any questions or inquiries, please contact [hpop.support@hhs.gov](mailto:hpop.support@hhs.gov)

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## **NEW: HHS Secretary Signs 11th Amendment to PREP Act for COVID-19 Medical Countermeasures**

On May 9, 2023, U.S. Secretary of Health and Human Services Xavier Becerra signed the [11th amendment to declaration under the Public Readiness and Emergency Preparedness \(PREP\) Act for medical countermeasures against COVID-19](#)

HHS Secretary issued this amendment:

- To clarify that COVID-19 continues to pose a credible risk of a future public health emergency
- To add two new limitations on distribution of Covered Countermeasures
- To extend the time period of coverage for certain Covered Countermeasures and Covered Persons
- To clarify the time period of coverage for Covered Persons authorized under the Declaration, and extended the duration of the Declaration to December 31, 2024

Read full details of the amendment in the [Federal Register Notice online](#)

The end of the COVID-19 Public Health Emergency Declaration does not automatically terminate PREP Act coverage. To learn more, view the [COVID-19 PREP Act FAQs online](#).

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Stakeholder Meeting: Federal Retail Pharmacy Therapeutics Program (FRPTP) Participants Monthly on Tuesdays (11:00 11:30PM CT)  
Next Session: June 20

Email [COVID19Therapeutics@HHS.gov](mailto:COVID19Therapeutics@HHS.gov) for zoom links to these meetings.

### **EUAs & Fact Sheets for COVID-19 Therapeutics**

To view the EUAs, fact sheets, and other resources associated with each COVID-19 therapeutic, select the links below:

- [Paxlovid](#)
- [Lagevrio](#)
- [Veklury](#) \*not provided by USG

### **Locating Therapeutics**

- [U.S. HHS COVID-19 Public Therapeutic Locator](#)
- [U.S. HHS Oral Antiviral Location Finder – including Test to Treat sites](#)

### **Contact Us**

If you have therapeutics-related questions, or if a member of your facility would like to be added to or removed from this newsletter’s mailing list, contact us by email at: [Therapeutics@dshs.texas.gov](mailto:Therapeutics@dshs.texas.gov).

## New: COVID-19 Therapeutics ASPR Webpages updates

ASPR webpages for COVID-19 Therapeutics [Paxlovid](#), [Lagevrio](#), and [Veklury](#) have been updated to include:

- Additional and updated FAQs
- Information that maps to the latest EUA/current approval for each product

For more information, please visit [COVID-19 Therapeutics | HHS/ASPR](#)

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## Reminder: Therapeutics Locator Tool to Include Outpatient Veklury(remdesivir) Providers

HHS has begun an initiative that will allow visibility of Veklury outpatient infusion sites on the [HHS COVID-19 Therapeutics Locator](#) to assist in matching patients at high risk of severe COVID-19 to the medications that can prevent disease progression.

- HHS requesting healthcare partners who order Veklury (remdesivir) for outpatient use to support improved public awareness and product access
- Any infusion site opting into this initiative will be featured on the COVID-19 Therapeutics Locator as an outpatient Veklury provider
  - Only information provided by the infusion site will be visible on the locator
  - Infusion sites can opt out of being on the locator at any time
  - Minimal engagement from the infusion sites required for their site to be shown on the locator

**If you want to have your site listed on the Outpatient Veklury (remdesivir) Locator, please click [here](#) to provide your information.**

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## UPDATE: Shelf-Life Extensions and Therapeutic Expiration Dates

**[REMINDER: No oral antivirals have expired at this time!](#)**

A searchable database of [COVID-19 Therapeutic Product Expiration Dates](#) is now available.

Search two ways:

- Use the search box to find a specific item or
- Select which product you are interested in and sort by lot number, labelled expiry, or extended expiry.

Pfizer is maintaining a [searchable expiry database](#) for Paxlovid (nirmatrelvir co-packaged with ritonavir). ASPR's expiry webpage includes the link to that site.

Learn more about shelf-life extensions and other COVID-19 therapeutic information in the ASPR [Important Updates](#) webpage.

**ALL COVID-19 therapeutics have received extensions for some or all lots. Please check with the manufacturer before removing any products from the proper storage conditions.**

### **Additional Shelf-Life Extension for Paxlovid**

**On January 18<sup>th</sup>, FDA authorized an additional extension to the shelf life from 18 months to 24 months for all lots of Paxlovid.**

- FDA granted this extension following a thorough review of data submitted by Pfizer. **To find the expiry date extension on your product, please download the data tables found on [ASPR's website](#).**

**For up to date information on expiration dates, please visit: [Important Updates | HHS/ASPR](#) and [Expiration Dating Extension | FDA](#)**

- FDA [Shelf-Life Extension for Paxlovid](#) (Jan 18, 2023); from 18 to 24 months\*no lots have reached expiry
- FDA [Shelf-Life Extension for Lagevrio](#) (Oct. 21, 2022); from 24 to 30 months\*no lots have reached expiry

Maintain all monoclonal antibodies under proper refrigerated temperatures, even if they are not currently authorized for use. It is possible that monoclonal antibodies will be authorized again in the future for use against new strains of SARS-COV2.

- [Shelf-Life Extension for Evusheld \(ASPR\)](#)
- [Shelf-Life Extension for Bebtelovimab \(ASPR\)](#)
- [Shelf-Life Extension for Bamlanivimab \(ASPR\)](#)
- [Shelf-Life Extension for Bamlanivimab and Etesevimab \(ASPR\)](#)
- [Shelf-Life Extension for REGEN-COV \(ASPR\)](#)
- [Shelf-Life Extension for Sotrovimab \(ASPR\)](#)  
**NEW!** FDA authorized a shelf-life extension from 24 months to 30 months for the GlaxoSmithKline monoclonal antibody sotrovimab. [Sotrovimab Fact Sheet for HCP](#)

**Update: No additional shelf-life extension is possible for etesevimab**

- Refer to online resources to determine true expiration date for etesevimab and bamlanivimab vials
- Product can be returned for destruction as a bam/ete patient course using expired ete with matching bam vial of earliest expiration date (patient course = 2 vials ete, 1 vial bam)

***NOTE: ASPR continues to work with product manufacturers to maximize shelf-life. We will provide any updates for upcoming expiration dates as soon as we receive.***

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